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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,908	02/23/2004	Henry R. Costantino	1733.1064-004	6133

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HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/784,908	COSTANTINO ET AL.	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/16/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A preliminary amendment of 7/16/04 canceled claims 23-60.

Claims examined on the merits are 1-22, which are all claims in the application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 and 13-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Mooney et al (6,281,015 B1) (listed on form 1449).

The claims are drawn to a method of administering cells to a patient comprising injecting into a treatment site of a patient a composition containing biodegradable, polymer microparticles and cells that provide a therapeutic effect in a patient. The therapeutic effect can be generation of new tissue.

Mooney et al disclose administering to a patient microspheres containing bioactive factors such as growth factors (TGFß), angiogenic factors or hormones such as insulin, glucagons and estrogen (col 8, lines 31-42) and cells that form cartilage (chondrocytes) (col 9, line 19). The cells and microspheres are suspended in or attached to a

polymer matrix (paragraph bridging cols 8 and 9). The microspheres and cells can be suspended in a polymer solution and injected into a patient prior to hardening of the suspension (col 9, lines 26-38, col 12, lines 1-9, and col 18, claims 3 and 4). The concentration of cells can be between 1 and 50 million cells/ml (col 12, line 8) such as $50x10^6$ cells/ml (col 16, line 51) or $5x10^7$ cells/ml (col 17, line 21).

Mooney et al disclose a method that is the same as presently claimed. The claims do not exclude the polymer matrix disclosed by Mooney et al. A morphogenic protein as in claims 20 and 21 is alternative to a growth factor and is not required by the claims when a growth factor is selected as the alternative.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 13-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Mooney et al (WO 96/18411) (listed on form 1449).

The claimed invention is described above.

The disclosure of Mooney et al (WO 96/18411) is the same as the disclosure of Mooney et al (6,281,015 B1).

Mooney et al (WO 96/18411) disclose the presently claimed method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mooney et al (WO 96/18411) or (6,281,015 B1) in view of Purchio et al (5,902,741) (listed on form 1449).

The claim requires the treatment site to be the articular space of a joint.

Mooney et al (WO 96/18411) and (6,281,015 B1) are described above.

Purchio et al disclose *in vitro* culturing of cells on a three-dimensional framework to produce cartilage tissue for use in repairing

articular cartilage of a joint (col 2, line 30 to col 3, line 21, col 6, lines 8-31, and col 15, lines 40-51).

It would have been obvious to produce articular cartilage as the cartilage produced by Mooney et al (WO 96/18411) or (6,281,015 B1) to obtain cartilage for use in repairing articular cartilage of a joint as suggested by Purchio et al.

Claim Rejections - 35 USC § 103

Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mooney et al (WO 96/18411) or (6,281,015 B1) in view of Holland et al (5,550,050) (listed on form 1449).

The claims require the secretion of a biologically active secretory molecule to provide the therapeutic effect.

Mooney et al (WO 96/18411) and (6,281,015 B1) are described above.

Holland et al disclose implanting in a host encapsulated secretory cells that release therapeutic substances (col 3, lines 19-25, and col 12, lines 15-20). The cells can be PC12 cells (col 6, line 33), pancreatic islet cells (col 9, lines 5-10) or adrenal chromaffin cells (col 15, lines 15-20). The therapeutic substance can be insulin (col 9, lines 39 and 49, and col 10, line 18) or dopamine (col 10, lines 28 and 31).

It would have been obvious to include secretory cells as cells implanted by Mooney et al (WO 96/18411) or (6,281,015 B1) to obtain the function of the cells to produce a therapeutic substance as suggested by Holland et al. Bioactive substances disclosed by Mooney

et al (WO 96/18411) or (6,281,015 B1) can be the same as therapeutic substances disclosed by Holland et al, and producing these substances or other therapeutic substances with secretory cells would have been obvious from the use of secretory cells taught by Holland et al.

Claim Rejections - 35 USC § 103

Claims 1-5 and 13-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mooney et al (WO 96/18411) or (6,281,015 B1) in view of Armstrong (5,830,507) and Dimoudis et al (5,980,888).

The invention and Mooney et al (WO 96/18411) and (6,281,015 B1) are described above.

Armstrong discloses forming skin replacement by treatment of a skin injury with a slurry of microspheres coated with cells.

Dimoudis et al disclose attaching keratinocytes to microcarriers to form a material for treatment of skin wounds.

It would have been obvious to omit the polymer matrix or polymer solution of Mooney et al (WO 96/18411) or (6,281,015 B1) and allow the cells to grow on the microspheres and produce tissue as suggested by Armstrong and Dimoudis et al using cells attached to microcarriers to form new skin tissue. The conditions of dependent claims are disclosed by (WO 96/18411) or (6,281,015 B1), or would have been obvious from conditions disclosed by the references.

Claim Rejections - 35 USC § 103

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-5 and 13-22 above, and further in view of Purchio et al.

The claimed invention and the references are described above.

When modifying Mooney et al (WO 96/18411) or (6,281,015 B1) by omitting the polymer matrix or polymer solution as set forth above, it would have been obvious to produce articular cartilage as the cartilage produced by Mooney et al (WO 96/18411) or (6,281,015 B1) to obtain cartilage for use in repairing articular cartilage of a joint as suggested by Purchio et al.

Claim Rejections - 35 USC § 103

Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-5 and 13-22 above, and further in view of Holland et al.

The claimed invention and the references are described above.

When modifying Mooney et al (WO 96/18411) or (6,281,015 B1) by omitting the polymer matrix or polymer solution as set forth above, it would have been obvious to include secretory cells as cells implanted by Mooney et al (WO 96/18411) or (6,281,015 B1) to obtain the function of the cells to produce a therapeutic substance as suggested by Holland et al. Bioactive substances disclosed by Mooney et al (WO 96/18411) or (6,281,015 B1) can be the same as therapeutic substances disclosed by Holland et al, and producing these substances or other therapeutic substances with secretory cells would have been obvious from the use of secretory cells taught by Holland et al.

Vogel et al (6,660,301 B1) is made of record to further disclose injecting microparticles and cells.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 and 13-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,719,970 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed method of injecting cells and microparticles would have been obvious from the method claimed by the patent of generating cartilage by injecting chondrocytes and microparticles.

Double Patenting

Claim 6 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,719,970 B1 in view of Purchio et al.

It would have been obvious to produce articular cartilage as the cartilage produced by method of the patent claims to obtain cartilage for use in repairing articular cartilage of a joint as suggested by Purchio et al.

Double Patenting

Claims 7-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,719,970 B1 in view of Holland et al.

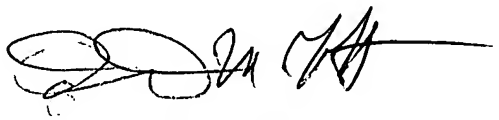
It would have been obvious to include secretory cells as cells implanted by the method of the patent claims to obtain the function of the cells to produce a therapeutic substance as suggested by Holland et al. Biologically active agents required by certain claims of the patent can be the same as therapeutic substances disclosed by Holland et al, and producing these agents with secretory cells would have been obvious from the use of secretory cells taught by Holland et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

DMN
4/4/06